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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,297	02/20/2004	Ning Qin	PRD-2041NP	7754

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EXAMINER

RAGHU, GANAPATHIRAM

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/783,297	<b>Applicant(s)</b> QIN ET AL.	
	<b>Examiner</b> Ganapathirama Raghu	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 8,10,17-21,23 and 25-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11-16,22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/11/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-64 are pending in this application for examination. Claims 1-7, 9, 11-16, 22 and 24 are now under consideration. Claims 8, 10, 17-21, 23, 25-49 and 50-64 remain withdrawn as they are drawn to non-elected inventions.

#### ***Election/Restrictions***

Applicant's election of Group I, claims 1-16, 22, 24 and 49 and SEQ ID NO: 3 for prosecution with traverse in their response dated Jan. 10, 2006 is acknowledged. Claims 17-21, 23, 25-49 and 50-64 are drawn to non-elected inventions and are withdrawn from further consideration.

The traversal is on the grounds that the SEQ ID NOs: 3, 5, 8 and 10 relates to similar aspects of one invention and can be examined and searched without overwhelming the Patent Office practices. However such an argument is not persuasive to withdraw restriction or rejoin distinct polynucleotide sequences that have different structures, Examiner continues to take the position that these sequences are different inventions, unless applicants identify with such evidence that the other non-elected sequences, SEQ ID NOs: 5, 8 and 10 are obvious variants or clearly admit for the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Furthermore claims 8 and 10 recite non-elected sequences, said claims are considered only to the extent of the elected sequence SEQ ID NO: 3 for examination. Examiner has now found that claim 49 is drawn to a method of identifying a compound that alters prostanoid

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synthesis catalyzed by human cyclooxygenase-3 and is not directed to method of making the polypeptide, it was inadvertently included in Group II as opposed to Group XI of the original restriction letter dated Nov. 17, 2005. Therefore, Examiner has removed claim 49 from Group I and placed it in Group XI.

Pursuant to 35 U.S.C. 121 and 37 CFR 1.141 and 37 CFR 1.143 Examiner is required to examine one elected polynucleotide sequence, as it is a search burden to examine the entire group, as the search involves sequence databases of patents, published and pending applications as well as non-patent literature. Therefore contrary to applicant's argument, the requirement is still deemed proper and is therefore made FINAL.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on Oct. 11, 2005 after the submission of the application on 02/20/2004 and is in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner has considered the IDS.

#### ***Drawings***

The drawings are considered for examination purposes only.

#### ***Specification: Sequence Compliance***

The disclosure is objected to because of the following informalities:

Applicants are required to comply with the sequence rules by inserting the sequence identification numbers of all sequences within the claims and /or specification. It is particularly

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noted that figures: 1A-E are sequences, but applicants fail to provide the SEQ ID NO: to these sequences in the figures or in the figure description of the specification. See particularly 37 CFR 1.821(d).

### ***Claim Objections***

Claims 8 and 10 are objected, because they are drawn to non-elected sequences.

### ***Claim Rejections: 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14 and 16 are rejected under 35 U.S.C. 101 because the claim could read on a non-statutory subject matter. The claim is drawn to a 'A recombinant host cell', which could still be an integral part of the host such as a human being. Claims directed to such matter are considered non-statutory. Examiner suggests amending the claim to recite 'An isolated recombinant host cell' in order to overcome the rejection.

### ***Claim Rejections: 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and claims 11 and 14 dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which applicant regards as the invention. Claims 1 and 2 recites the phrase "...80% identity to SEQ ID NO: 3... and 70% identity to SEQ ID NO: 4...", the metes and bounds of the phrase is not clear and the Examiner suggests changing the phrase to "...80% sequence identity to SEQ ID NO: 3... and ...70% sequence identity to SEQ ID NO: 4... " respectively.

Claims 4 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 7 recites the phrase "...cyclooxygenase-3 enzyme". It is not clear as to how those skilled in the art would able to distinguish from the already known cyclooxygenases (Cox), Cox-1 and Cox-2 just by activity alone without the structural limitations (sequence information). Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 9, 11-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3, 9, 11-16 are directed to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 80% identity to SEQ ID NO: 3 or a nucleic acid encoding an

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amino acid sequence having 70%, 80% or 90% identity to SEQ ID NO: 4, wherein the encoded amino acid has no function or nucleic acid molecule comprising at least 12 sequential bases of SEQ ID NO: 3 or the complementary sequence thereof, expression vectors and host cells comprising said polynucleotides. Claims 1-3, 9, 11-16 are rejected under this section 35 U.S.C. 112 because the claims are directed to a “genus” of polynucleotides with no support in the specification for the structural details associated with the function. No description of identifying characteristics or functional characterization recognizing all of the sequences have been provided in the specification. The specification discloses the isolation of only a single polynucleotide with SEQ ID NO: 3 an intron region coding for polypeptide having the amino acid sequence of SEQ ID NO: 4. No information, beyond the characterization of a polypeptide comprising SEQ ID NO: 4 as having Cox-3 activity has been provided by the applicants, which would indicate that they had possession of the claimed genus of the polynucleotides, short oligomers or complementary sequence thereof. The disclosed information is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 4-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one of

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skilled in the relevant art that the invention(s), at the time the application was filed, had possession of the claimed invention.

Claims 4-7 are directed to a genus of nucleic acids encoding a polypeptide having Cox-3 activity and comprising amino acids 1-30 of SEQ ID NO: 4. The specification does not contain any disclosure of the structure of all nucleic acid sequences included in the claimed genera. The genus of nucleic acids claimed is large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally distinct nucleic acids are encompassed within the scope of the claims. The specification discloses only a single species of claimed genus (i. e. that of SEQ ID NO: 3), which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. A sufficient written description of a genus of DNAs may be achieved by a recitation of structural features common to members of genus, **which features constitute a substantial portion of the genus**. The recited structural feature of the genus (i.e., encodes a polypeptide comprising a fragment of 30 amino acids of SEQ ID NO: 4) does not constitute a substantial portion of the genus as the remainder of the structure of any nucleic acid encoding a polypeptide having the Cox-3 enzyme activity is completely undefined and the specification does not define the remaining structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).



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Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such away as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 is directed to a method of expressing any human Cox-3 protein including variants, mutants and recombinants in a recombinant cell by introducing an expression comprising a polynucleotide (variants, mutants and recombinants) vector capable of encoding said human Cox-3 protein into a host cell and culturing the host cell under conditions that allow expression of the human Cox-3 protein. No structural relationship is disclosed of all the polynucleotides encompassed by the claims and one cannot extrapolate or predict the structure of these polynucleotides named by functional characteristics alone. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Claims 1-7, 9, 11-16, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide of an intron region with SEQ ID NO: 3 encodes a polypeptide of SEQ ID NO: 4 through RNA editing, vectors and host cells comprising the polynucleotides, does not reasonably provide enablement for any

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polynucleotide having 80% nucleic acid sequence identity to SEQ ID NO: 3 and the corresponding polypeptides or any polynucleotide encoding a polypeptide having, 70%, 80% or 90% amino acid sequence identity to SEQ ID NO: 4, or any polynucleotide comprising at least 12 nucleotides of SEQ ID NO: 3, encoding a polypeptide having Cox-3 activity and an amino acid sequence identity of at least 70%, 80% or 90% to SEQ ID NO: 4, vectors and host cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1-7, 9, 11-16, 22 and 24 are so broad as to encompass any polynucleotide sequence that has 80% sequence identity to SEQ ID NO: 3 and the corresponding polypeptides or any polynucleotide encoding a polypeptide having 70%, 80% or 90% amino acid sequence identity to SEQ ID NO: 4, or any polynucleotide comprising at least 12 nucleotides of SEQ ID NO: 3, encoding a polypeptide having 70%, 80% or 90% amino acid sequence identity to SEQ ID NO: 4 vectors and host cells. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and encoded polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional

properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence of only one polynucleotide with SEQ ID NO: 3 encoding the polypeptide with SEQ ID NO: 4. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides and that are simply 80% identical to SEQ ID NO: 3 or polynucleotides encoding a amino acid sequence that is 70%, 80% or 90% identity to SEQ ID NO: 4. The specification is limited to teaching the use of SEQ ID NO: 3 as the polynucleotide which encodes the polypeptide SEQ ID NO: 4, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make and use the claimed polynucleotides and polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence

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where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide encoding a polypeptide with 80% identity to the nucleic acid sequence of SEQ ID NO: 3 or any polynucleotide encoding Cox-3 polypeptide having 70%, 80% or 90% identity to SEQ ID NO: 4 or any polypeptide encoded by a polynucleotide comprising 12 nucleotide sequence identity to SEQ ID NO: 3, because the specification does not establish: (A) a rational and predictable scheme for identifying specific polynucleotide and encoded polypeptide with an expectation of obtaining the desired biological function; (B) regions of the protein structure which may be modified without affecting the activity, (C) the general tolerance of the polynucleotide to modification and the extent of such tolerance without affecting the activity of the encoded polypeptide, (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful and (E) does not teach how one skilled in the art would use a polypeptide encoded by a polynucleotide comprising at least 12 nucleotides of SEQ ID NO: 3.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim broadly including polynucleotides and polypeptides with an enormous number of modifications. The scope of the claim must bear a reasonable correlation with the scope of

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enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polynucleotides and polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

### ***Claim Rejections 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 9 and dependent claims 11, 13-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., (Biochem. Biophys. Res. Commun., 190(2): 406-411, 1993). Claims 1 and 3 is drawn to a polynucleotide that is at least 80% identical to SEQ ID NO: 3 or the complementary sequence thereof and to an isolated nucleic acid molecule comprising at least 12 sequential bases of SEQ ID NO: 3 or the complementary sequence thereof. Claims 11, 13-14 and 16 are drawn to vectors and host cells comprising the polynucleotide of claims 1 and 3 and the method of expressing the encoded polypeptide. Wang et al., (*supra*), disclose an isolated polynucleotide (Accession NO: L08404) sequence, which has 100% homology to the SEQ ID NO: 3, designated as the promoter of human prostaglandin H synthase-1 gene. The reference also discloses vectors and host cells comprising said polynucleotides (Materials and Methods section, paragraph 6, page 407). Therefore, Wang et al., (*supra*) anticipate claims 1, 3, 9, 11, 13-14 and 16 as written (see copy of the sequence alignments provided).

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and dependent claims 11-16, 22, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Simmons et al., (USPGPUB: US2003/0220306 A1, publication date Nov. 27, 2003 and claiming the priority date of Provisional Application No.: 60/326133 filed on 9/28/01). Claims 1-6, 11-16, 22 and 24 are drawn to a polynucleotide that is at least 80% identical to SEQ ID NO: 3 or the complementary sequence thereof and to an isolated nucleic acid molecule comprising at least 12 sequential bases of SEQ ID NO: 3 or the complementary sequence thereof, encoding a polypeptide comprising an amino acid sequence of at least 70%, 80% or 90% sequence identity and having a Cox-3 enzyme activity, vectors, host cells, method of making the polypeptide and a kit comprising the said polynucleotides. Simmons et al., (*supra*), disclose an isolated polypeptide that exhibits Cox activity, having 96.6% sequence identity to SEQ ID NO: 4 of the instant application. Simmons et al., also disclose the encoding polynucleotides, vectors, host cells, and method of making the polypeptide. Therefore, Simmons et al., (*supra*) anticipate claims 1-6, 11-16, 22 and 24 as written (see copy of the sequence alignments provided).

Claims 1 and 3, dependent claims 11, 13-14 and 16 are rejected under 35 U.S.C. 102 (e) as being anticipated by Blumenfeld et al., (US patent NO: 6432648 B1. date of patent 08/13/2002, claiming the priority date of US application 60/119917, filed on 02/12/1999). Claims 1 and 3 are drawn to a polynucleotide that is at least 80% identical to SEQ ID NO: 3 or the complementary sequence thereof and to an isolated nucleic acid molecule comprising at least 12 sequential bases of SEQ ID NO: 3 or the complementary sequence thereof. Blumenfeld et al., (*supra*) disclose an isolated polynucleotide (SEQ ID NO: 320) sequence, which has 88.2% homology to the SEQ ID NO: 3, designated as biallelic markers derived from genomic regions carrying genes involved in arachidonic acid metabolism. The reference also discloses primers/complementary sequences hybridizing to regions flanking these polynucleotides, vectors and host cells (Column 121, Example 7). Therefore, Blumenfeld et al., (*supra*) anticipate claims 1 and 3, dependent claims 11, 13-14 and 16 as written (see copy of the sequence alignments provided).

Claims 1 and 3 are rejected under 35 U.S.C. 102 (e) as being anticipated by Venter et al., (US patent NO: 6812339 B1. date of patent 11/02/2004, claiming the priority date of US application 60/231498, filed on 09/08/2000). Claims 1 and 3 are drawn to a polynucleotide that is at least 80% identical to SEQ ID NO: 3 or the complementary sequence thereof and to an isolated nucleic acid molecule comprising at least 12 sequential bases of SEQ ID NO: 3 or the complementary sequence thereof. Venter et al., (*supra*) disclose isolated polynucleotide (SEQ ID NOs: 15685 and 11879) sequences, which has 88.2% homology to the SEQ ID NO: 3, designated as polymorphisms in known genes associated with human disease, methods of

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detection and uses thereof. The reference also discloses primers/complementary sequences hybridizing to regions flanking these polynucleotides. Therefore, Venter et al., (*supra*) anticipate claims 1 and 3 as written (see copy of the sequence alignments provided).

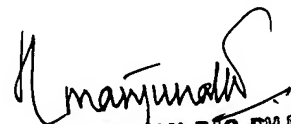
### ***Conclusion***

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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